PVA/PVOH TSCA Section 21 Petition & Safer Choice Discussion

December 14, 2022

Global Product Stewardship

Safety • Sustainability • Regulatory • Technical Relations

What We Plan To Show Today

- PVA used in detergents is not plastic, it is fully soluble just like many other ingredients used in similar consumer products
- PVA is not a solid particle and cannot associate with and transport other chemistries
- PVA is safe for human health
- PVA is safe for the environment
- PVA meets low priority substance safety criteria and is accepted by Safer Choice
- PVA enables consumer delight and sustainability benefits when used in detergents
- PVA-based films are mixtures of ingredients that have been assessed following USEPA guidelines and are all safe for humans and the environment

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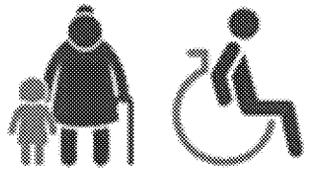
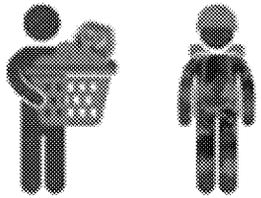
PVA Films Used in Detergent Pods Enable Significant Consumer and Sustainability Benefits

INDEPENDENCE

97% OF CONSUMERS SAY LAUNDRY PACS MAKE LIFE EASIER

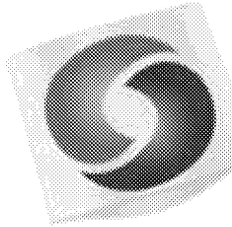


Lightweight & pre-measured for safe & effective use by senior citizens and people with disabilities

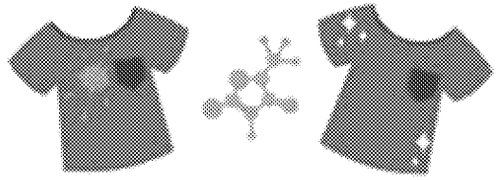


Portable & convenient in the city, on campus and military bases

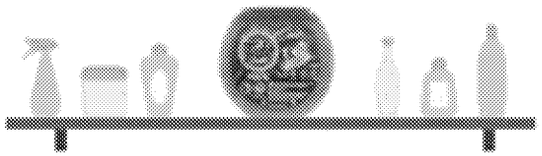
INNOVATION



3-CHAMBER COMPACT DESIGN ENHANCES CLEANING PERFORMANCE



2x more concentrated formula providing just the right amount of cleaning power



No need for separate pre-treaters or brighteners

Benefits of washing in cold

Washing in cold is not only beneficial for you and your wallet, but for the environment, too.

Save money

Washing in cold water can save you up to $150 a year on your energy bill.*(1)

Help the environment

You can save 90% of the energy of every load of laundry on average just by switching from hot to cold which reduces the impact of a load of laundry on the environment significantly.

Get a great clean

Tide cleans better in cold water than the bargain brand does in warm.*(2)*

27+ million

tons of CO2 avoided

Impact of moving from 50% of NA loads in Cold to 75% over the decade

= 10X P&G Annual Operations

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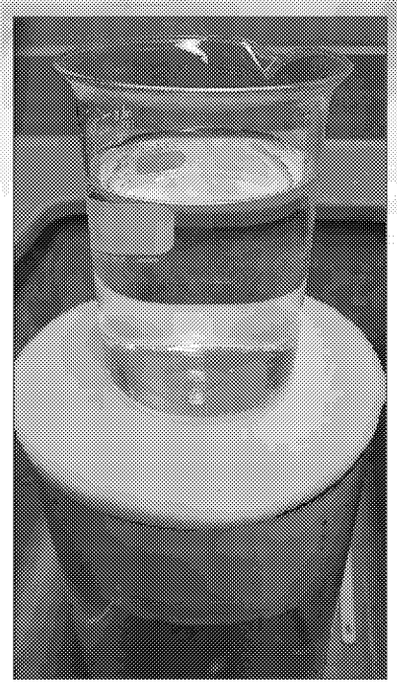
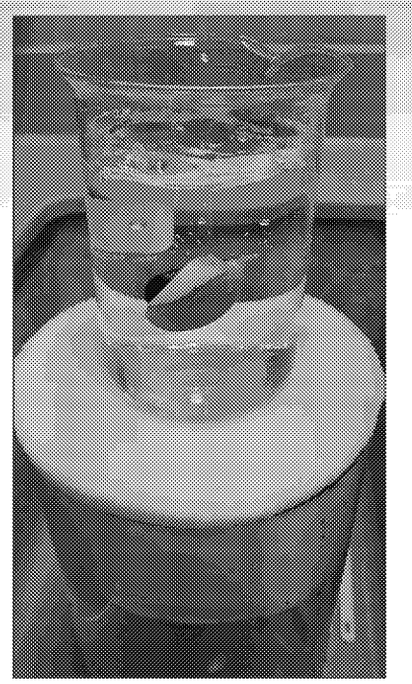
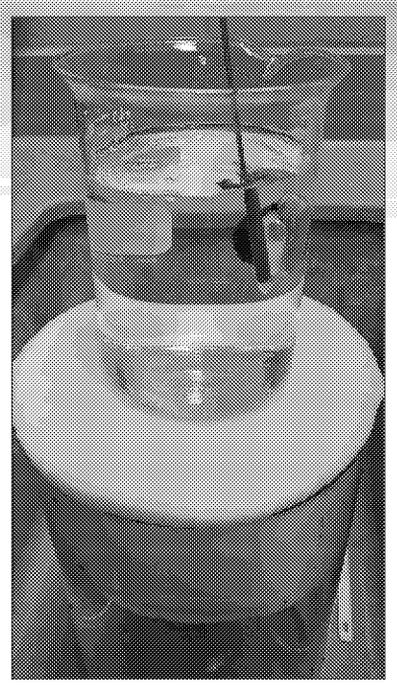
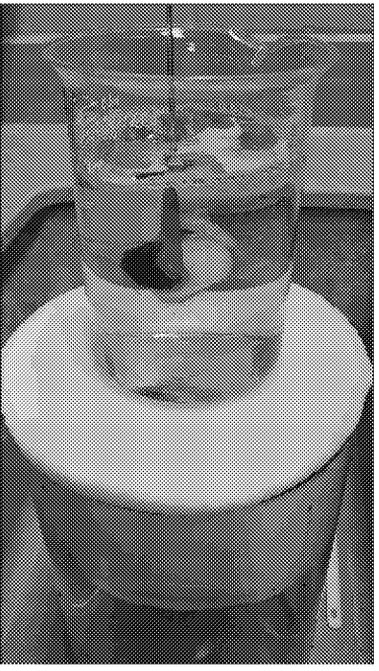
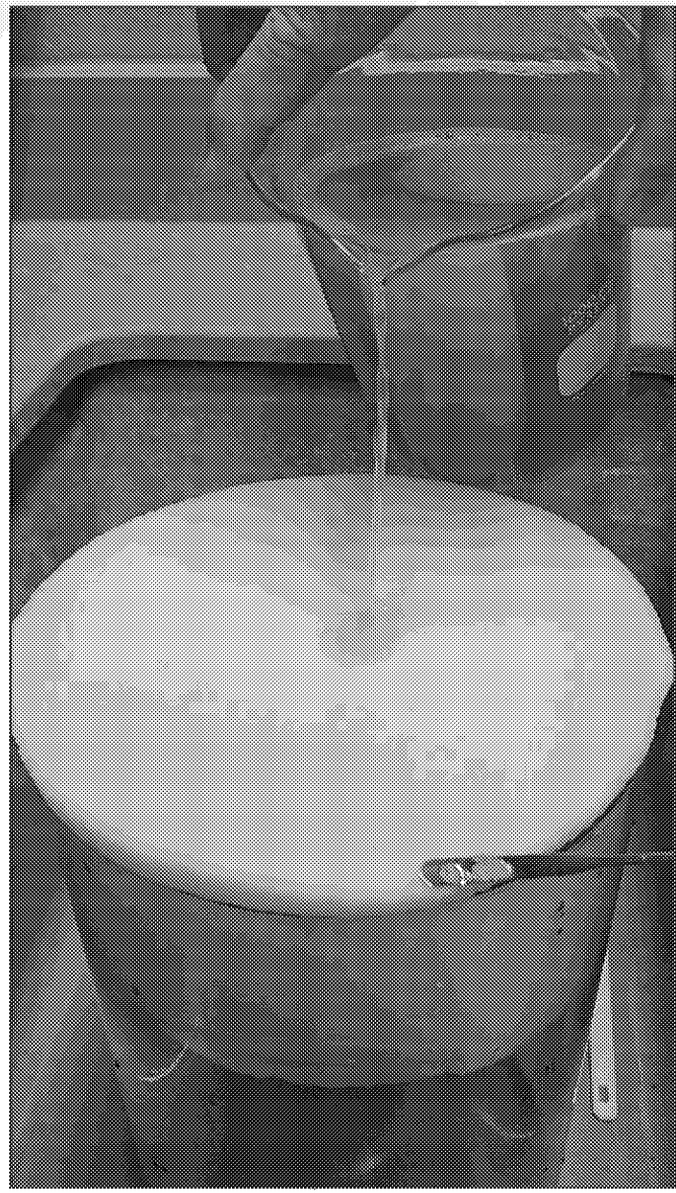
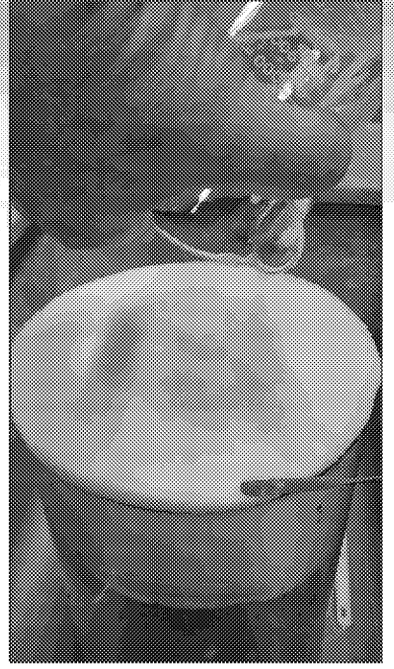
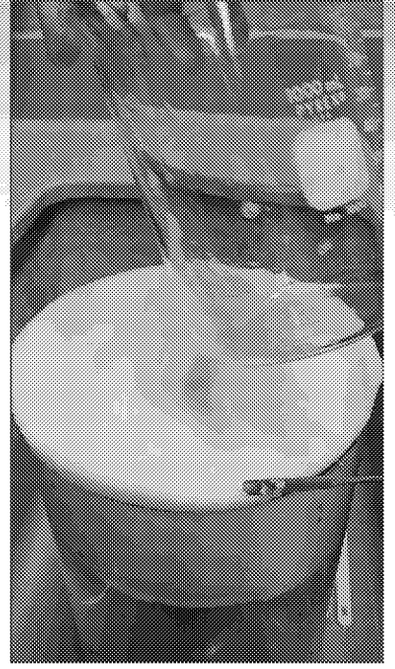
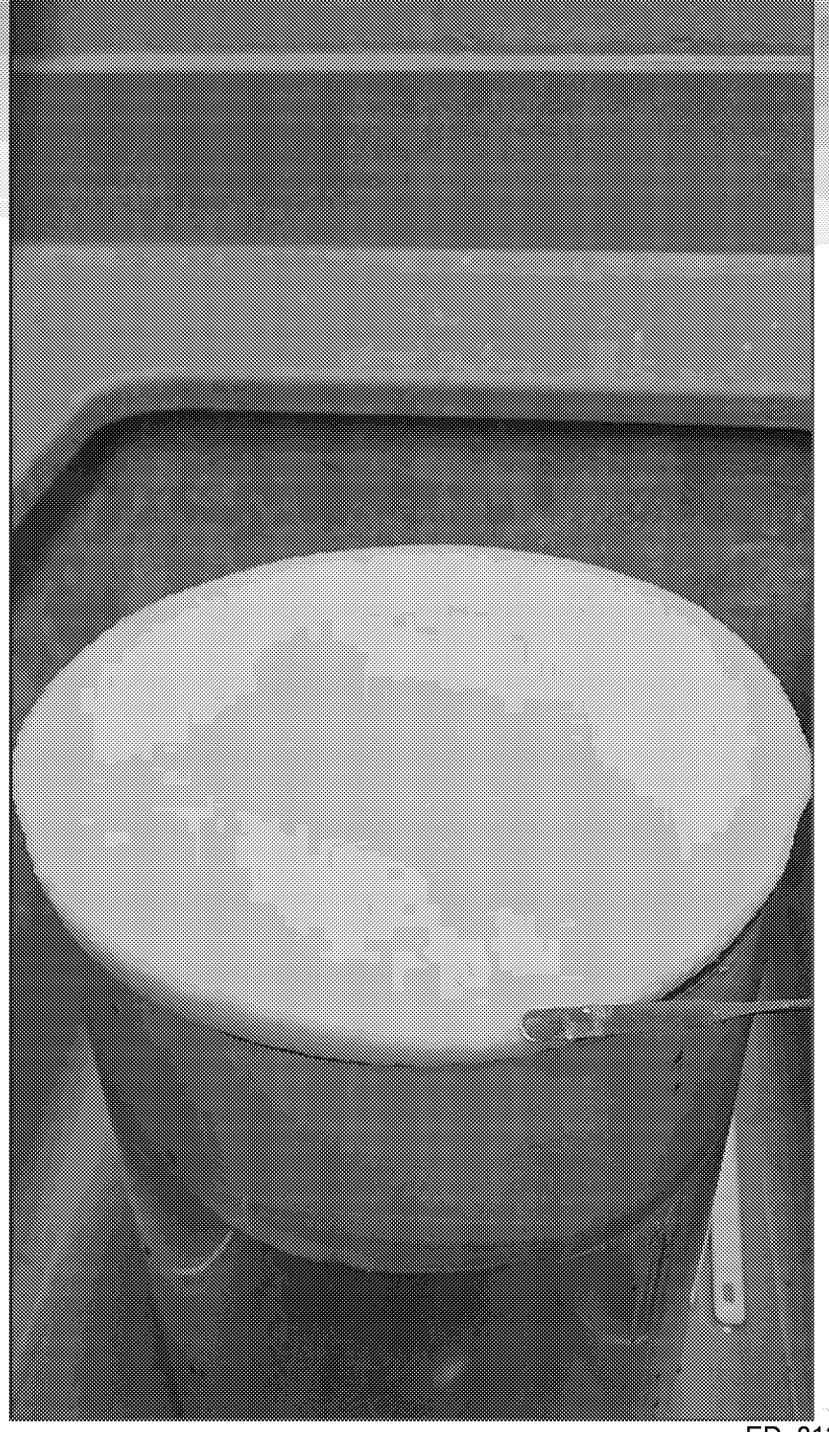
Not plastic: PVA Films Are Designed to Dissolve Rapidly and Completely

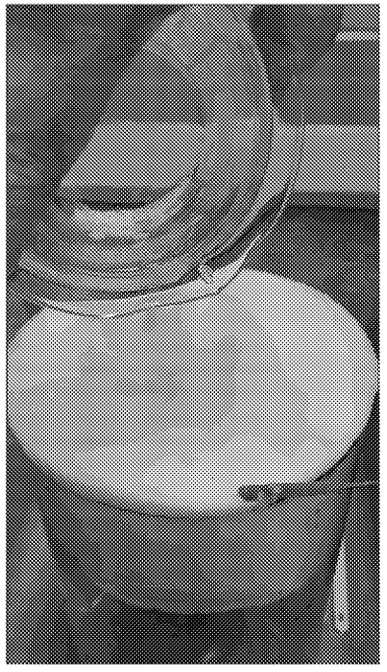
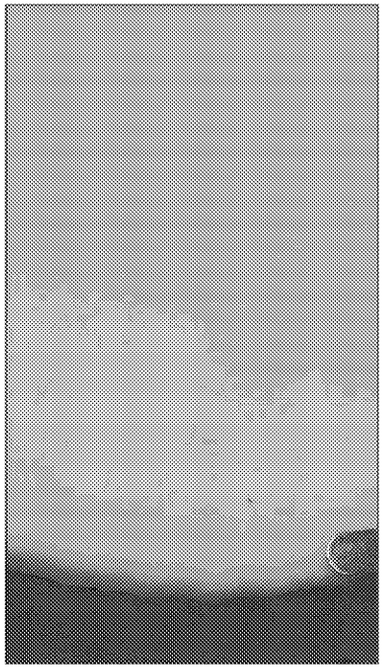
PVA films are soluble in water ≥10 g/L





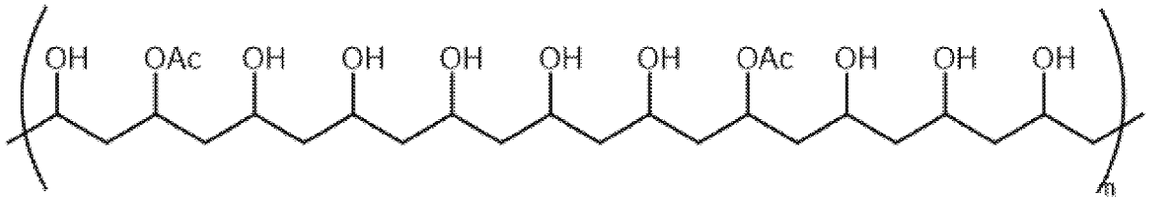





Polyvinyl Alcohol Safer Choice Listings & Chemistry

Safer Choice Listings

Code	Common Name	CAS Registry Number	Functional Use
	Polyvinyl alcohol	9002-89-5	Polymers
	Vinyl acetate vinyl alcohol polymer	25213-24-5	Polymers



PVA Chemistry

- PVA is not prepared by polymerization of vinyl alcohol as it is thermodynamically unstable with respect to its tautomerization to acetaldehyde.
- Instead, PVA is prepared by polymerization and subsequent hydrolysis of polyvinyl acetate.
- The PVA utilized in unit dose films and in pharmaceuticals is partially hydrolyzed (85-90%) polyvinyl acetate.

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Human Health: PVOH Meets Low Priority Substance & Safer Choice Criteria

Endpoint	Value	EPA Low Concern Criteria	Meets Criteria?
Acute Oral LD_{50}	1,500-22,000 mg/kg[1]	>2,000 mg/kg	☑
Repeat Dose, Neurotoxicity & Immunotoxicity (90-day)	>5000 mg/kg/day[1]	> 100 mg/kg/day	☑
Reproductive & Developmental Toxicity	>5000 mg/kg/day[1]	> 250 mg/kg/day	☑
Mutagenicity / Genotoxicity	Negative[1]	Negative for chromosomal aberrations and gene mutations, or no structural alerts	☑
Carcinogenicity	Negative in intravaginal NTP 2-year study. [1, 2, 3, 5]	Negative studies or robust mechanism-based SAR	☑
Skin Sensitization	Negative in GPMT[3] Negative in HRIPT[3]	Adequate data available and not GHS Category 1A or 1B	☑
Respiratory sensitization	No direct hazard data. Weight of evidence indicates lack of respiratory sensitization. Most respiratory sensitizers test positive in skin sensitization assays.[4] No known human respiratory sensitization adverse events with abundant use in cosmetics, including sprays.[3]	Adequate data available indicating lack of respiratory sensitization	☑
Eye Irritation / Corrosivity	Not irritating[3]	Clearing in less than 24 hours, mildly irritating	☑
Skin Irritation / Corrosivity	Mild to no irritation at 72 hours[2, 3]	Mild or slight irritation at 72 hours	☑

*The degree of hydrolysis is between 86.5% and 89%. Molecular weight: Ranges from 24,000 to 150,000 g/mol.

[1]GRAS notice No. 767
[2]The EFSA Journal (2005) 294:1-15
[3]CIR (1998)
[4]Arts (2020)
[5]NTP TR 474

P&G Global Product Stewardship

Polyvinyl Alcohol Used in Detergent Films is Safe for the Environment

PVOH used in detergent films must be cold water soluble. Narrow range of structures meet this criteria. PVOH with these structural characteristics will be discussed:

- Degree of Hydrolysis (DH) range 85-90%
- Molecular weight (MW) range: ~44,000-230,000

PVOH used in P&G detergent films are safe for the environment and:

- Readily biodegradable in screening studies
- Fully mineralized in screening studies
- Highly removed in wastewater treatment via biodegradation
- Fully mineralized in river water
- Have low ecotoxicity
- Have low bioconcentration potential
- EFAST evaluations show negligible risk
- Meet USEPA criteria for low priority substances

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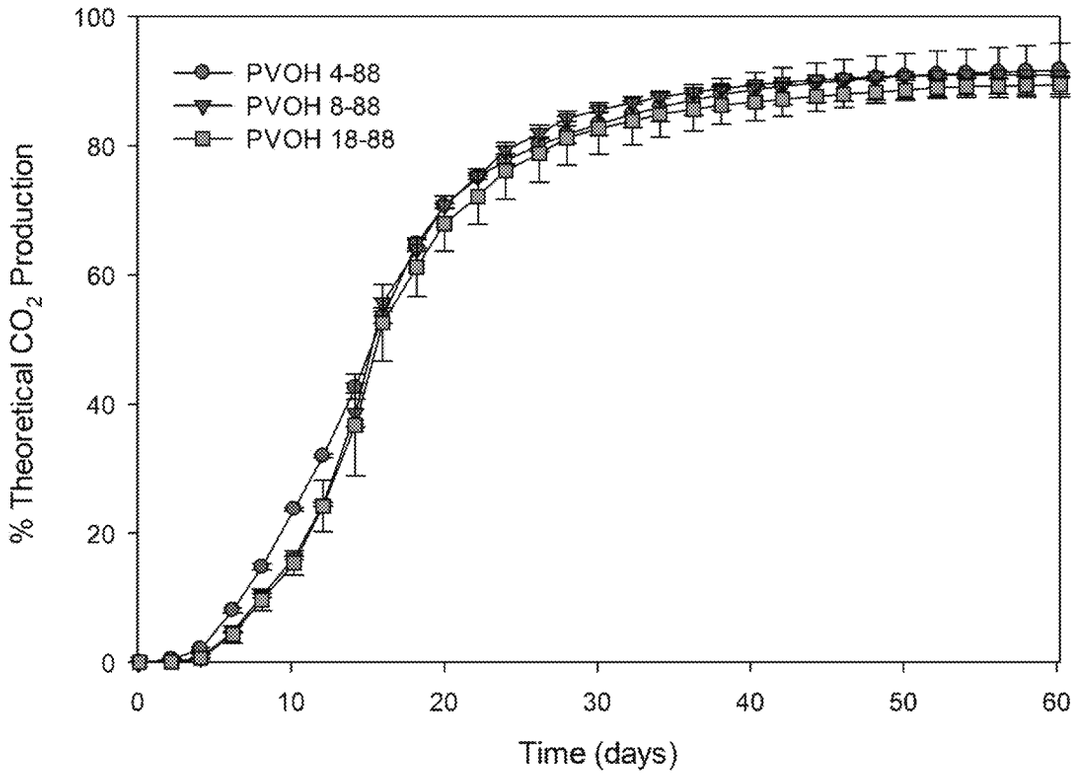
PVOH is Ready-Biodegradable and Completely Mineralized in Screening Studies



Material	Mw	DH (mol %)	Viscosity (mPa-s)
PVOH 4-88	31,000	88	3.8
PVOH 8-88	67,000	87.5	8.4
PVOH 18-88	130,000	87.8	17.5

- OPPTS 835.3110 /OECD 301B guideline compliant study published
- PVOH in MW and DH range used in detergent films
  - All were ready biodegradable (>60% ThCO2 evolution in 28 d, meet 10 d window)
  - All completely mineralized, negligible DOC remaining (>90% ThCO2 evolution and <4.3% DOC)

OPPTS 835.0001 "*Ready biodegradability tests are designed so that positive results are unequivocal. Given a positive result in a test of ready biodegradability, it may be assumed that the chemical will undergo rapid and ultimate biodegradation in the environment. In such cases, no further investigation of the biodegradability of the chemical, or of the possible environmental effects of transformation products, is normally required.*"

Menzies J, Wilcox A, Casteel K, McDonough K. 2023. Water soluble polymer biodegradation evaluation using standard and experimental methods. Science of the Total Environment. 853: 3.
USEPA. 2008. OPPTS 835.0001 Principles and Strategies Related to Biodegradation Testing of Organic Chemicals Under the Toxic Substance Control Act (TSCA). EPA 712-C-08-008

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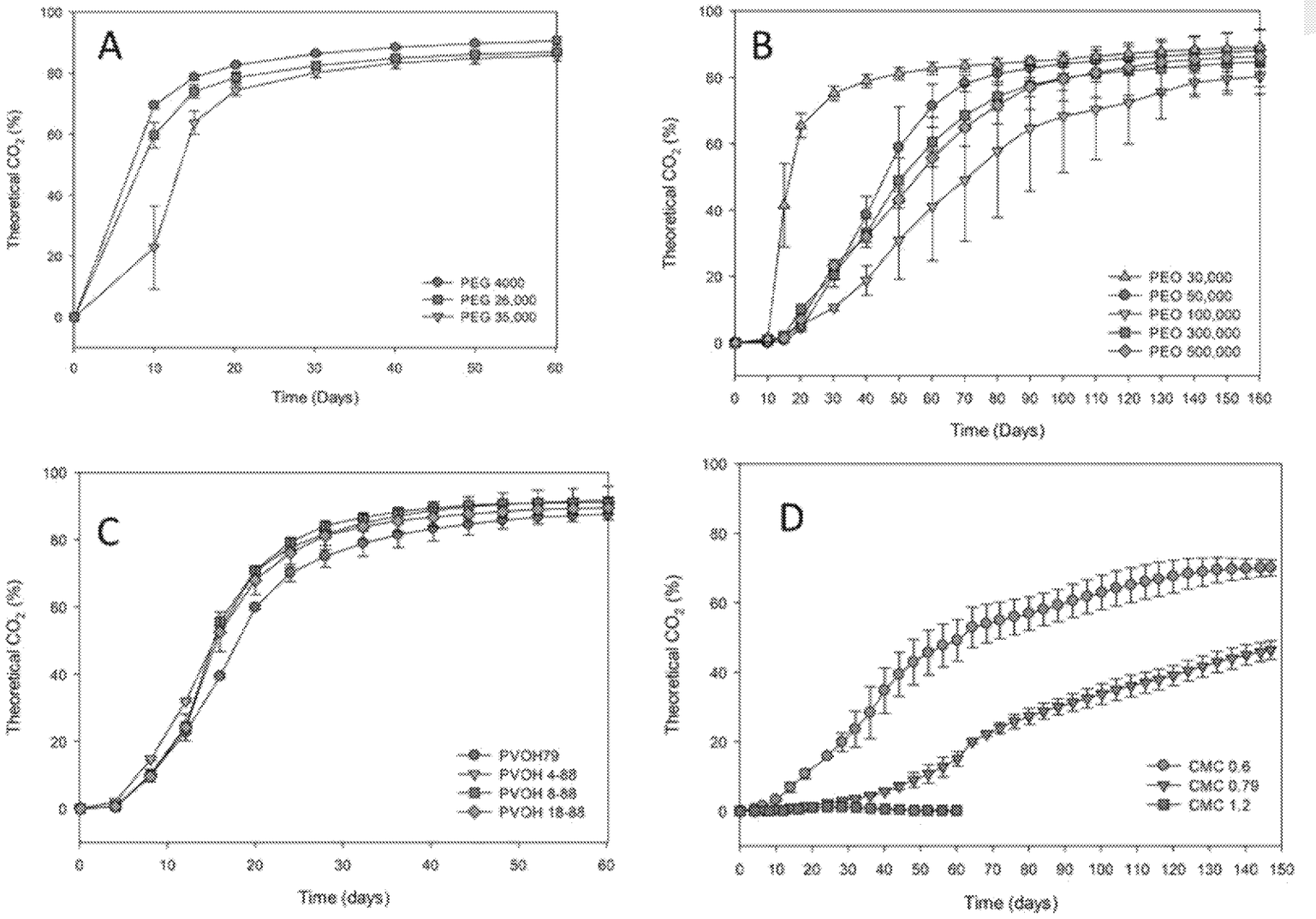
PVOH Biodegraded Similarly or Better Than Other Water-Soluble Polymers



- OPPTS 835.3110/OECD 301B guideline compliant study published
- PVOH in MW and DH range used in detergent films biodegraded rapidly and completely
- PVOH biodegraded at a similar rate and to a similar extent as PEG materials
- PVOH biodegraded faster and to a higher extent than any carboxymethyl cellulose evaluated

Menzies J, Wilcox A, Casteel K, McDonough K. 2023. Water soluble polymer biodegradation evaluation using standard and experimental methods. Science of the Total Environment. 853: 3.

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Based on USEPA Default Rates for Environmental Modeling of Ready-Biodegradable Chemicals, High Removal of PVOH via Biodegradation in Wastewater Treatment and Surface Water is Expected

Wastewater Treatment Default Biodegradation Rates

Table I Proposed Scheme		
Ready test result	Inherent test result	Activated sludge half-life, hr
pass test	--	1
no pass, but >= 40%	--	3
no pass: >+ 20 but < 40%	>= 0%	10
>=20 but < 70%	30	
no pass: < 20%	< 20%	10,000, or current default for no biodeg if different;

Surface Water Default Biodegradation Rates

Table I Proposed Scheme			
Ready test result	Inherent test result	Water half-life, d	Rate constant
pass test	--	5	0.14 d-1
no pass, but >= 40%	--	10	0.069 d-1
no pass: >= 20 but < 40%	>= 70%	30	0.023 d-1
--	>= 20% but < 70%	100	0.0069 d-1
no pass: <20%	< 20%	10,000, or other default for no biodeg as appropriate	(k = 0)

If the EPISUITE STP model is run for a water soluble, ready-biodegradable polymer like PVOH, removal estimates would be 94% during wastewater treatment

Reference: https://www.epa.gov/tsca-screening-tools/interim-guidance-using-ready-and-inherent-biodegradability-tests-derive-input#methods

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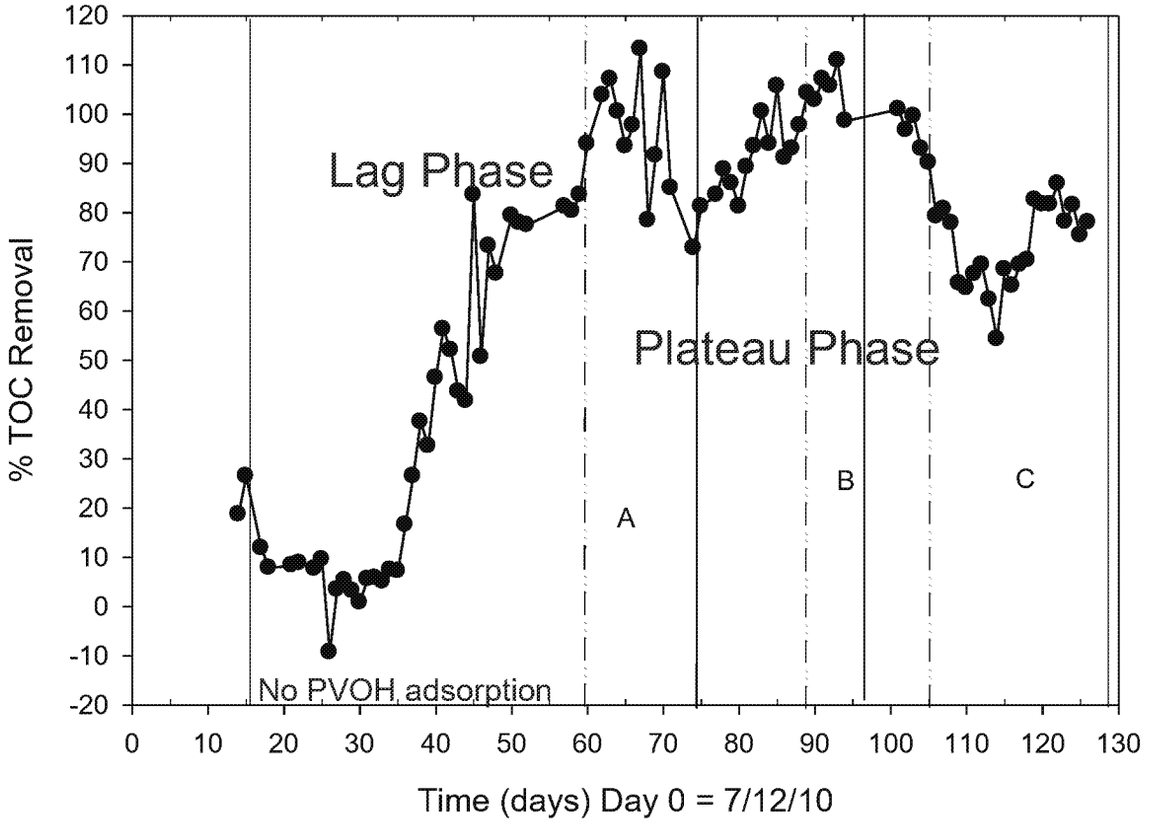
Simulation Study Confirmed High Removal Of PVOH Due to Biodegradation During Wastewater Treatment



A = 20 day SRT removal
B = 15 day SRT removal
C = 10 day SRT removal

- Guideline Compliant OPPTS 835.3240/OECD 303A Simulation Test Aerobic Sewage Treatment: Activated Sludge Units
- High Removal via biodegradation after lag phase
  - No adsorption to activated sludge during initial dosing phase
  - Structurally similar test materials are ready biodegradable in OECD 301B

Test Period	SRT	Removal (%)
Removal Period A	20	94.1 ± 11.4
Removal Period B	15	101.7 ± 5.4
Removal Period C	10	75.9 ± 10.6
Total Removal Pd	variable	**87.0 ± 13.9**

As expected, based on data from other chemicals, OECD 301 Ready Biodegradation Screening Studies accurately predicted high removal due to Biodegradation in a WWTP simulation study

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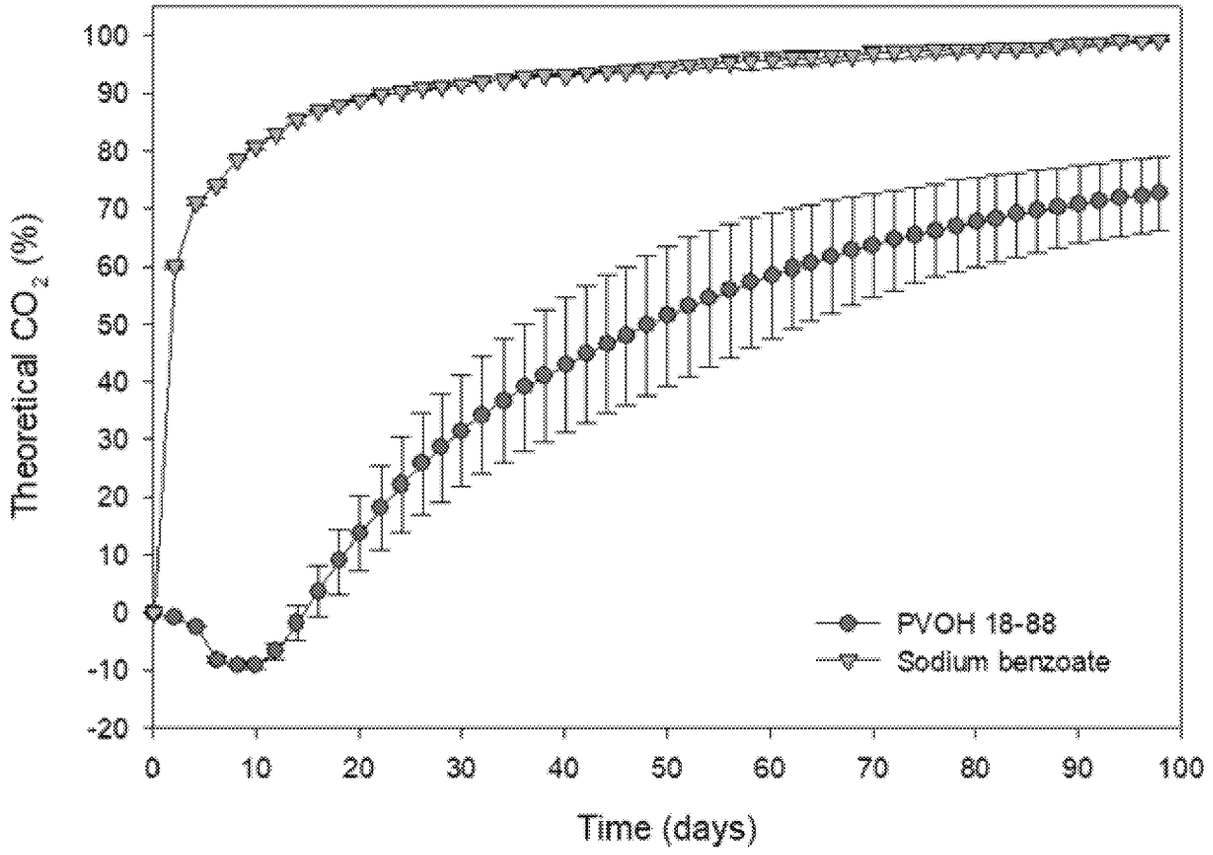
Microbes in River Water Can Completely Mineralize PVOH



- Modified OPPTS 835.3110/OECD 301B Ready Biodegradability study
- River water served as inocula and test media
- PVOH 18-88 mineralized completely reaching 71.9 ± 6.5% ThCO2 evolution in 95 d with negligible DOC remaining (3.5 ± 2.8%)

Based on PVOH 18-88 being ready biodegradable a default half-life of 5 days in river water is predicted under actual environmental conditions

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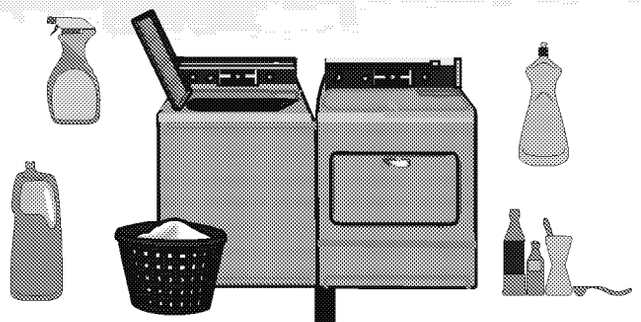
PVOH Down the Drain Fate Summary



- **Microbial communities present in wastewater treatment and river water can rapidly and completely mineralize PVOH**
- **Low levels of PVOH that will enter aquatic environment are safe due to the very low ecotoxicity of PVOH**

PVOH is water soluble and moves through a sewer to WWTP

Sewer

PVOH biodegrades extensively during WWT (87 to >90%)

X Biosolids

Soil is not a dominant compartment for PVOH Fate

Effluent

Any non-degraded PVOH leaves WWTP in effluent

PVOH can completely mineralize In surface water

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PVOH Aquatic Toxicity Concern is Low

Test Material PVOH 18-88

Trophic level	Acute Toxicity	Chronic Toxicity
OECD 236 *D. rerio*	**96-hr LC50 > 1000 mg/L**	**ACR=10, NOEC > 100 mg/L**
OECD 202 *D. magna*	**48-hr LC50 >1000 mg/L**	**ACR=10, NOEC > 100 mg/L**
OECD 201 *R. subcapitata*	**72-hr ErC50 >1000 mg/L** **96-hr ErC50 >1000 mg/L**	**NOEC > 1000 mg/L**

USEPA New Chemical Program defines aquatic toxicity concern levels as (EPA-748-B12-001):

	Low Concern (mg/L)	Moderate Concern (mg/L)	High Concern (mg/L)
Acute	> 100 mg/l	1 - 100 mg/l	< 1 mg/l
Chronic	> 10 mg/l	0.1 - 10 mg/l	< 0.1 mg/l

These experimental results align with historic understanding of PVOH and nonionic polymer ecotoxicity:

- Arfsten et al 2004 published toxicity data on a PVOH homopolymer with lower MW and DH, acute fish and invertebrate LC/EC50 values of >572, and 442 mg/L and algae NOEC of 320 mg/L
- Boethling and Nabholz published review of polymer toxicity data submitted to US EPA PMN program. Authors conclude “if a nonionic polymer is water soluble or dispersible and has monomers reacted via random order, then aquatic toxicity is still low with base set LC50/EC50 values expected to be >100.0 mg/L.”
- Recent data on other nonionic polymers provides additional evidence that nonionic polymers are not aquatically toxic (e.g., polyethylene glycol, PEGs – Duis et al 2021)

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PVOH has Low Bioconcentration Potential

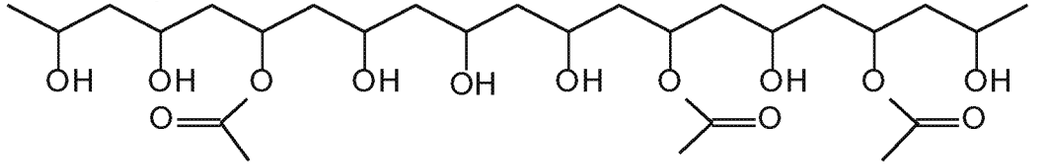
PVOH is not a solid particle and will not associate with or transport other chemistries

Polymer size influences bioconcentration potential therefore regulatory thresholds have been established based on molecular weight:

- A threshold of MWn > 1000 Da is generally applied as indicating “polymers of low concern” (US EPA 1997 TSCA)
- ECHA threshold of Mw >1100 Da designates “not B” (ECHA-17-G-12-EN)

Bioconcentration Factor Predictions from Episuite:

- Various PVOH oligomers (3mer-75mer) were modeled with ranging degrees of hydrolysis (70-100%)



- BCF factor is stable across the various oligomers BCF = 3

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E-FAST evaluations show no acute or chronic risk
PVOH Environmental Safety is Assured

Acute Aquatic Risk Characterization: 1Q10 for the 10th percentile (23.36 µg/L) is > 1000-fold lower than the acute COC for the most sensitive species (200,000 µg/L) indicating low acute risk.

Chronic Aquatic Risk Characterization: ZERO days of exceedance against the chronic COC indicating low chronic risk.

WWTP Removal (%) [a]	Volume (mT/year) [b]	Acute COC (µg/L) [c]	Chronic COC (µg/L) [c]	7Q10 Flow (µg/L) [d]	1Q10 Flow (µg/L) [d]	Number of days per year the COC is exceeded	Risk
87.0	7400	200,000	10,000	23.36	23.36	0.00	Low Acute and Chronic risk

[a] Average removal in the OECD 303A Wastewater Treatment Plant Simulation Study (87.0 ± 13.9%)
[b] Chemical Economic Handbook volume estimate for the US 2022 consumption of polyvinyl alcohol in water-soluble films
[C] Calculated for most sensitive endpoints based on EPA Guidance (EPA-748-B12-001)
[d] For the 10th percentile facility as calculated by E-FAST Version 2.0

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PVOH Meets EPA Low Priority Substance and Safer Choice Criteria

Environmental Fate and Effects	PVOH Data	Meets Low Priority Criteria?
Aquatic Acute Toxicity	LC/EC50 >1000 mg/L	Yes
Aquatic Chronic Toxicity	LC/EC10 >100 mg/L	Yes
Persistence	chemical meets the 10-day window as measured in a ready biodegradation test	Yes
Bioaccumulation Potential	MW>1000 Da	Yes

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